## REMARKS

Claims 24-27, 29, 39, 40, 44, 45 and 48-51 are pending. Claims 25, 27 and 46-51 are canceled without prejudice. Claims 24 and 25 are amended. New claim 52 is presented herein. Upon entry of the amendments and new claim directed herein, claims 24, 26, 29, 39, 40, 44, 45 and 52 will be pending. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

Rejections under 35 U.S.C. §112, Second Paragraph:

Claims 24 and 48 are rejected under 35 U.S.C. §112, second paragraph as indefinite. The Office Action states that claim 24 "is indefinite because it claims '...an isolated peptide which binds to and stabilizes the native conformation of the first polypeptide, in which the peptide comprises a fragment of a second polypeptide, said fragment comprising 600 amino acids or fewer of said second polypeptide..." The Office Action states that there are several problems with this claim, including "1) a fragment of a second polypeptide is not disclosed and the full structure of the polypeptide is also not disclosed, therefore it is impossible to imagine what is the structure of the fragment, where a fragment of a polypeptide could be a single amino acid such as lysine, for example; 2) said fragment is comprising 600 amino acids or fewer, therefore once again the fragment could be a single amino acid such as lysine. Therefore the invention is not specifically disclosed and the claim is indefinite." Applicants respectfully disagree.

First, applicants note that the possibility that the claim may read on a single amino acid does not raise an indefiniteness issue. One of skill in the art would immediately recognize whether a given peptide falls within the scope of the "600 amino acids or fewer" limitation, so even if the term does encompass a single amino acid, the claim term is not indefinite.

Second, claim 24 as proposed to be amended does not recite a "fragment" or a "fragment comprising 600 amino acids or fewer." As such, the rejection will be moot upon entry of the amendment.

Claim 48 is also rejected as indefinite for recitation of the limitation "said peptide comprising 200 amino acids or fewer." Again, one of skill in the art can immediately determine

whether a given peptide falls within the scope of that limitation, so the term is not indefinite. However, the cancellation of claim 48 herein renders this rejection moot.

Rejections under 35 U.S.C. §112, First Paragraph:

Claims 24 and 48 are rejected under 35 U.S.C. §112, first paragraph for lack of written description.

First, the cancellation of claim 48 herein renders the rejection moot with respect to that claim.

With respect to claim 24, the Office Action states:

> "Claim 24 does not satisfy the written description requirement because the structure of a full sequence of the peptide or its fragments is not provided. If the full sequence of the claimed polypeptide is not disclosed then any fragment of the unknown polypeptide cannot be ascertained. The claim states that the fragment is comprising 600 amino acids or fewer, which is meaningless, and thus the sequence structure of the polypeptide must be provided. Further, the written description requirement is not satisfied because the structure of the fragment (600 amino acids or fewer) does not correspond with its function."

Applicants respectfully disagree.

Applicants note that it is the specification which satisfies the written description requirement with respect to a claim, and not the claim itself. Thus, if the specification describes the subject matter of the claim such that one of skill in the art would recognize that the Applicant was in possession of the invention as claimed, the requirement is satisfied. More specifically, the recitation of the term "fragment of a second polypeptide" does not, in itself, present a written description issue where the specification provides a written description of a second polypeptide and of fragments of the polypeptide within the scope of the claim. Nonetheless, Applicants note that claim 24 as proposed to be amended does not recite a fragment of a second polypeptide. Rather, the claim as amended recites "an isolated peptide of SEQ ID NO: 1 which binds to and stabilizes the native conformation of a human p53 polypeptide, but not a denatured conformation of the p53 polypeptide." The claim as proposed to be amended therefore specifically recites not only the human p53 polypeptide, but also the identity of the peptide, i.e., SEQ ID NO: 1, which

binds to and stabilizes the native conformation of the human p53 polypeptide. The specification clearly describes a peptide of SEQ ID NO: 1 which binds to and stabilizes the native conformation of a human p53 polypeptide. See, for example, page 34, lines 1-6 and throughout the Examples. As such, the specification satisfies the written description requirement with respect to claim 24 as proposed to be amended. Reconsideration and withdrawal of the §112, first paragraph rejection of this claim is respectfully requested.

Rejection under 35 U.S.C. §102(b):

Claims 24-27, 29, 44, 45 and 48-51 are rejected under 35 U.S.C. §102(b) as lacking novelty over Naumovski et al. The Office Action states:

> Naumovski et al. teach the structure of Bcl2-binding protein ("Bbp") that specifically interacts with p53 protein in vivo, where the Bbp necessary (sic) requires for its binding to the p53 a specific ankyrin repeats and SH3 domain. See Figure 1, page 3886, where a fragment of less than 200 amino acids that contains ankyrin repeats and the SH3 domain is depicted in Figure 1(a). Figure 3, page 3887 shows binding of Bbp protein to p53. (Claims 24, 25, 44 48)
>
> Figure 6, page 3888, shows an amino acid sequence of Bbp (SEQ ID NO: 1) which contains REDEDEIEW amino acid sequence, as part of the SH3 domain necessary for binding of the Bbp protein to p53. The REDEDEIEW amino acid sequence of Bbp protein is identical to the instant invention (Claims 24, 27, 45, 49-51). See Figure 1 and Figure 6, where the fragments of less than 600 or 200 amino acids are known.
>
> Therefore, the claims are anticipated by Naumovski et al. because the REDEDEIEW amino acid fragment of Bbp protein is identical to claims 27, 45, and 49-51 of the instant invention, and the amino acid fragment has the same function of binding p53 domain."

Applicants respectfully disagree.

First, the Naumovski et al. reference does not teach an isolated peptide of SEQ ID NO: 1 as recited by the claims as proposed to be amended. Contrary to the statement in the Office Action that "the claims are anticipated by Naumovski et al. *because the REDEDEIEW amino acid fragment of Bbp protein is identical to claims 27, 45 and 49-51 of the instant invention*," the reference nowhere teaches an isolated peptide of SEQ ID NO: 1 as claimed in claim 24 as

amended. While the Bbp polypeptide reported by Naumovski et al. may comprise an REDEDEIEW (SEQ ID NO: 1) subsequence as part of its 1005 amino acid sequence, the Naumovski et al. reference simply does not teach an *isolated peptide* of this sequence. Further, the reference does not teach any function for such an isolated peptide of SEQ ID NO: 1, and particularly not binding to and stabilizing the native conformation of a human p53 polypeptide, but not a denatured conformation of the p53 polypeptide as required by claim 24 as proposed to be amended. As such, the reference cannot anticipate the invention of claim 24 as proposed to be amended or of claims that depend from it.

Applicants note that where claim 45 recites a pharmaceutical composition comprising a peptide *consisting of* the sequence REDEDEIEW (SEQ ID NO: 1) together with a pharmaceutically acceptable carrier, diluent or excipient, the claim cannot be anticipated by the Naumovski et al. reference because, as discussed above, the Naumovski et al. reference in no way teaches a peptide consisting of the REDEDEIEW (SEQ ID NO: 1) sequence.

Rejection under 35 U.S.C. §102(e):

Claims 24 and 29 are rejected under 35 U.S.C. §102(e) as anticipated by Winnacker et al. The Office Action states that Winnacker et al. teach chaperones Hsp60 that bind to prion protein $PrP^C$. Applicants respectfully disagree.

Applicants submit that Winnacker et al. does not teach a peptide of SEQ ID NO: 1 as required by all claims upon entry of the amendments proposed herein. As such, the reference cannot anticipate the claims as amended. Reconsideration and withdrawal of the rejection is respectfully requested.

New claim 52 and the amendment language:

Finally, new claim 52 is drawn to an isolated peptide consisting of the sequence REDEDEIEW (SEQ ID NO: 1). Naumovski et al. does not teach such an isolated peptide and cannot, therefore, anticipate this claim. Applicants submit that a peptide consisting of REDEDEIEW, as recited, for example, in claim 45 and former claim 51 has been considered during this prosecution and should therefore not require additional search; the new claim should

be entered in this after-final amendment. The same is also true for the amendments to claim 24, because the "SEQ ID NO: 1" and "human p53" limitations have already been considered by the Examiner during this prosecution in, e.g., claims 25, 26, 50 and 51. That is, the amendments proposed herein do not raise new issues and Applicants respectfully request that they be entered.

In view of the foregoing remarks, all issues relevant to patentability raised in the Office Action have been addressed. Applicants respectfully request entry of the proposed amendments and reconsideration of the claims.

Respectfully submitted,

Date: September 19, 2006

Name: Mark J. FitzGerald
Registration No.: 45,928
Customer No.: 29933
Edwards Angell Palmer & Dodge LLP
P.O. Box 55874
Boston, MA 02205
Tel.: (617) 239-0100